



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Suk Cho et al.

Art Unit : 1615

Serial No. : 09/800,195

Examiner : C. Evans

Filed : March 6, 2001

Title : DIETARY SUPPLEMENT COMPOSITIONS

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Commissioner for Patents

Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132 OF LYNN PERKES

I, Lynn Perkes, declare as follows:

1. I am a citizen of the United States and presently live at 41 Jerry Lane, Rexburg, ID 83440.
2. I am presently employed by Melaleuca, Inc., and have been so employed since 1992.
3. I received a M.S. degree in 1986 from Brigham Young University in Kinesiology and Exercise Physiology.
4. I am listed as an inventor on the above-indicated patent application.
5. I have read the above-referenced patent application, the pending claims, the WO 99/07400 reference, of which I am a named inventor, the Gaynor *et al.* patent, and the Examiner's Office Actions mailed July 3, 2002 and February 3, 2003.

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

September 3, 2003

Date of Deposit

Angela J. Montgomery

Signature

Angela J. Montgomery

Typed or Printed Name of Person Signing Certificate

6. I am aware that in the Office Action mailed February 3, 2003 the Examiner suggested that Applicants demonstrate in a side-by-side comparison the results obtained using (1) the grape seed extract of the cited reference, i.e., WO 99/07400 and (2) the claimed composition.

6. As a named inventor on the WO 99/07400 reference, I am familiar with the compositions disclosed therein, including the PROVEXCV™ and PROVEXCV2™ compositions described on pages 17-18 and 20-21, respectively. Both compositions contain a grape seed extract, grape skin extract, and an enzyme blend.

7. Results from *ex vivo* platelet aggregation tests conducted on dogs administered PROVEXCV™ and PROVEXCV2™ are set forth on pages 24 and 27, respectively, of WO 99/07400. They indicate that platelet aggregation activity decreased  $40\% \pm 9\%$  and  $42\% \pm 10\%$  after administration of 10 mg/kg of PROVEXCV™ and 15 mg/kg PROVEXCV2™, respectively.

8. By comparison, a composition described in the present application administered at 5 mg/kg Muscat grape seed extract, 20 mg/kg grape skin extract, and 2 mg/kg enzyme blend demonstrated a 60% reduction in *ex vivo* platelet aggregation activity. See pages 18-19 of the present Specification.

9. The difference between the  $40\% \pm 9\%$  or  $42\% \pm 10\%$  reductions achieved with the compositions cited in WO 99/07400 and the 60% reduction achieved with a composition containing Muscat grape seed extract is substantial and unexpected from the teachings of WO 99/07400.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States

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Code and that such willful false statements may jeopardize the validity and/or enforceability of the instant patent application or any patent issuing thereon.

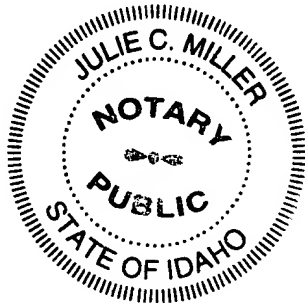
Dated: Sept. 2, 2003

Lynn Perkes  
Lynn Perkes

STATE OF Idaho )  
 ) ss.

COUNTY OF Bonneville )

Before me this 2<sup>nd</sup> day of Sept, 2003, personally appeared Lynn Perkes known to me to be the person whose name is subscribed to the foregoing Declaration, and acknowledged that he executed the same as his free act and deed for the purposes therein contained.



Julie C. Miller  
Notary Public  
Comm. Expires 2-18-09